SUBJECT: Reconciliation of the Serious Adverse Events Database under the caBIG™ Program	SOP No.: CR-007
	Issue No.: 1.0
	Issue Date: 10/31/2005
	Page 1 of 5 Pages

Standard Operating Procedure –

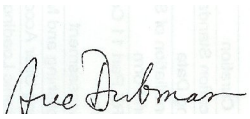
Reconciliation of Serious Adverse Events Database under the caBIG™ Program

This cover sheet controls the layout and components of the entire document.

Issued Date: September 19, 2005

Effective Date: October 31, 2005

Department Approval:



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QA Approval:

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Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	09/19/2005	SOP Working Group	N/A	Initial release.

1. Purpose

This Standard Operating Procedure (SOP) describes the procedure for reconciling serious adverse events reported during the conduct of a clinical research trial in the clinical database with serious adverse events (SAEs) recorded in the Safety Database. Reconciliation is performed to assure that serious events are accurately and captured, interpreted, and consistently reported to regulatory authorities.

2. Scope

2.1 This SOP applies to all clinical trial research studies sponsored by the National Cancer Institute (NCI) and covered under the oversight of the caBIG™ Program.

2.2 This SOP applies to all clinical trial research studies where SAEs reporting to regulatory authorities is required (i.e., under investigational new drug (IND) or new drug applications (NDAs), not in the product's current labeling, unexpected, post-marketing studies).

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3. Requirements

3.1 Reconciliation of SAEs captured during the conduct of clinical research trials and SAEs recorded in the Safety Database will occur several times during the lifecycle (the conduct) of the clinical research trial.

3.2 Timing and number of the reconciliation cycles will be determined by the frequency of data received, the scheduling of safety updates and the timing of interim and final reports to regulatory authorities on serious adverse event findings.

3.3 The capture of SAEs in both the clinical trials database and the safety database should be standardized with regard to data captured and coding of terms (e.g., event description, start and stop date, relation to study drug, verbatim term coding, etc.).

3.4 All information (data and metadata elements) to be reconciled during this procedure shall be identified and documented in the study plan before the first patient is enrolled in the clinical research protocol.

3.5 A cut-off point will be identified in the study plan, after which, no SAEs will be added to the clinical research database, even if the safety database is updated.

3.6 Changes to either database, as a result of reconciliation activities, will be made in a timely manner to expedite clinical study closure activities and/or safety reporting requirements.

3.7 Quality Assurance formally conducts a review of the reconciliation results for accuracy.

3.8 Changes to either database will be updated, documented and maintained appropriately, in compliance with 21 CFR Part 11 requirements.

4. References /Regulations/Guidelines

4.1	N/A	CDISC Glossary
4.2	CR-001	SOP for Study Conduct

5. Roles & Responsibilities

Role	Responsibility
Study Coordinator	• Work with the Drug Safety Officer and the Clinical Research Study Team to reconcile SAEs captured in the clinical data management application with SAEs captured and recorded in the Safety Database. • Make the necessary changes and/or updates to the clinical data management application.
Drug Safety Officer	• Assist in reconciling SAEs in line with this SOP • Make the necessary changes and/or updates to the Safety Database.
Clinical Study Team	• Provide the necessary clinical information or interpretation input on SAEs captured during the conduct of the clinical research trial, including input on coding of events.
Quality Assurance	• Conduct a formal review of the reconciliation processes and performs a quality check on updates to the databases.

6. Attachments

This SOP will be used in conjunction with the attachments identified below. These attachments must be used by all research sites conducting clinical trials under the caBIG™ Program and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

Title	Description
1) Procedure Description for Reconciliation of SAEs	This document provides instructions for reconciling SAEs. It provides step-by-step guidance to ensure that all SAEs collected during the conduct of a clinical research trial and the SAEs collected and recorded in the Safety Database are reconciled in a consistent manner.

Title	Description
2) SAE Data Reconciliation Form	This form captures and tracks changes made during the reconciliation process, providing the documented evidence for appropriately addressing and documenting reconciliation activities and resulting changes to the clinical data management application and the Safety Database.
3) Process Flow for SAE Reconciliation	This document identifies the workflow activities, by role, for the steps identified in the Procedure for Reconciliation of SAEs.